

ORIGINAL RESEARCH PAPER

## Patient's knowledge, attitudes and practices on informed consent in a clinical setting; A study done at Colombo North Teaching Hospital, Sri Lanka

Perera WNS<sup>1\*</sup>, Perera BPP<sup>2</sup>, Paranitharan P<sup>1</sup>

<sup>1</sup> Department of Forensic Medicine, Faculty of Medicine, University of Kelaniya, Sri Lanka.

<sup>2</sup> Forensic Physicians' Service, the Orchard Clinic, Royal Edinburgh Hospital, Morningside Terrace, Edinburgh.

### ABSTRACT

**Introduction:** The signing of a consent form is a process with legal and ethical implications. It is required that informed written consent be obtained from a patient for an invasive procedure after proper explanation of the risks, benefits and alternative procedures.

**Objective:** To determine knowledge, attitudes and practices related to informed consent among patients.

**Materials and Methods:** A cross sectional descriptive study was carried out over a period of one year in a Tertiary care hospital in Sri Lanka. The participants were medical or surgical inward patients who were 18 years or above, who had consented to invasive procedure or surgery. The quantitative data of 420 patients were analyzed.

**Results:** Majority (96%) agreed that consent is important in medical practice. Many (61%) were of the view that it helps to make an informed decision. Majority (92%) preferred a doctor, who can explain more in the consent process than a nursing officer (11%). However, 61% were of the view that consent should be taken from the patient and relatives both, even if the patient is competent of giving consent. Majority of the participants (84%) wanted to discuss with family members before giving consent.

**Conclusion:** Majority of patients were aware of the concept of consent in medical practice and preferred the doctor and family members to be involved in the decision-making process. This finding is important to adopt a doctor-patient-family model in the consent taking process while respecting the patient's wishes.

**Keywords:** Informed consent, patient, autonomy, reasonable patient based standard, doctor-patient-family model

**Corresponding Author:** Perera W.N.S  
nirperera2000@yahoo.com  
ORCID iD: <https://orcid.org/0000-0002-8733-7364>

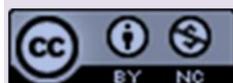
#### Article History

Received: 12.03.2021

Received in revised form: 27.08.2021

Accepted: 14.09.2021

Available online: 01.12.2021



This article is licensed under the terms of the Creative Commons Attribution-Non Commercial 4.0 International License.

### INTRODUCTION

Informed consent had been a necessary requirement for medical treatment, medical research and donation of human tissue and organs for the past few decades in Sri Lanka<sup>1,2</sup>. In Asian countries like Sri Lanka, where paternalism is entrenched in culture, concepts such as 'informed consent' are not as equally understood as in the West<sup>3</sup>.

Consent is obtained by giving sufficient information to a competent patient or to the next of kin or legal guardian to make decisions on therapeutic process or participation in research after being educated of the purpose, procedure, alternatives, risk, benefit and outcome<sup>4,5</sup>.

Even though multiple purposes of informed consent such as legal, ethical and administrative compliance overlaps with each other<sup>6</sup>, most importantly it protects the patient's right for self-determination<sup>7,8</sup> and it will promote the patient's 'autonomy'<sup>9</sup>, which is considered to be one of the four principles of medical ethics. It is also thought to act as a protection against coercion, deceit, abuse and exploitation<sup>10</sup>. It strengthens the trust between the physician and his patient<sup>11</sup> and gives the patient a sense of 'ownership' of his decision<sup>12</sup>. The current practice that the patient signing on the Bed Head Ticket (BHT) giving consent for 'any surgery' does not help the patient understand this process<sup>13,14</sup>. In contrast, signing a formal consent form with understanding allows the patient to be truly informed, while respecting the patient's autonomy and giving protection to the doctor, reducing malpractice claims<sup>15</sup>.

## OBJECTIVE

To determine the knowledge, attitudes and practices of hospitalized patients on 'informed consent'.

## MATERIAL AND METHOD

A cross sectional descriptive study was carried out over a period of one year in a Tertiary care hospital in Sri Lanka. The participants were medical or surgical inpatient patients. The admission registry in the ward was perused on convenient days and every other patient who was admitted to the ward who was 18 years or above, who had consented to invasive procedure or surgery were included in the study. Their BHT was scrutinized to assist selection based on inclusion and exclusion criteria. Patients who were not competent enough to give informed consent or seriously ill to provide information were excluded from the study.

The sample size was calculated as 420, keeping a margin of error of 5 % and a confidence interval (CI) of 95%.

Information was gathered using an interviewer administered questionnaire with the consent from the patient, by a trained pre-intern medical officer. The questionnaire was constructed based on the literature<sup>16,17</sup> and consisted of the following sections; (a) demographic details of the patient (b) knowledge of the patient regarding the consent process (c) attitudes to consent and (d) practices related to the giving of consent. The types of consent which can be given as a gesture or verbal or written was introduced to the patient in the 3rd, 5th and 7th

questions in Table 1. Before administering it was pilot tested on ten patients. The modified version was assessed for face and content validity.

Attitudes of the patients were assessed on a 5-point Likert scale. "Strongly agree" and "agree" were summed up to "agree", and "strongly disagree" and "disagree" were summed up to "disagree" during analysis. Descriptive statistics were applied to analyze the study using SPSS version 19.

Ethical clearance for the study was obtained from the Ethics Review Committee, Faculty of Medicine, Ragama. Permission to conduct the study was obtained from the hospital administration.

## RESULTS

### Characteristics of the participants

Majority of patients were female (55%). Forty one percent were in the 18-40-year category while 38% were between 41 to 59 and 21% over 60 years. The mean age was 42 years. A significant majority (94%) had been educated beyond the 5th grade with 13% having received higher education. A majority were Buddhist (62%).

Knowledge regarding consent was high among participants. Majority of patients expressed that verbal consent was adequate in vaginal or anal examination (Table 1).

Majority of participants agreed that the consent process helped to make a decision with understanding. However most of them were of the view that consent should be taken both from the patient and relatives even if the patient was of sound mind (Table 2).

A majority of patients (93%) preferred a doctor to obtain consent than a nursing officer.

### Perceptions regarding practices in the ward during the process of obtaining consent

A majority agreed that they received adequate information (77%), discussed with family members (84%) and understood the procedure adequately (74%) before giving consent. However, 47% said that they gave consent because they trusted the doctors (47%) while 21% said they gave consent without properly reading or listening to the information given.

**Table 1: Patients knowledge on consent in medical practice**

Statement	Yes (%)	No (%)	Not sure (%)	Mean score
Do you know that 'consent' is important in medical practice?	95	4	1	1
Is consent needed for simple examination such as listening to the heartbeat?	25	75	-	2
If consent is needed what type of consent is sufficient for above mentioned procedure? *	Gesture 76	Verbal 23	Written 1	
Is consent needed for vaginal or anal examination?	82	17	1	1
What type of consent is sufficient for above mentioned procedure? *	Gesture 14	Verbal 68	Written 18	
Is consent needed for invasive investigations such as coronary angiogram?	93	7	-	1
What type of consent is sufficient for above mentioned procedure? *	Gesture 5	Verbal 12	Written 83	
Consent of next of kin can be taken if the patient is incapable of giving consent such as unconscious.	94	5	1	1
Consent should be taken from the patient if patient is capable of giving consent.	92	7	1	1
It is not necessary to take consent from the patient if surgery is necessary for life saving.	77	23	-	1
Should risks/ complications be informed to the patient during consent taking?	95	3	1	1
12. Should desired benefits/ outcomes of the procedure be informed to the patient during consent taking?	95	3	2	1
Can the patient refuse medical treatment including surgery even if the doctors feel that it is for patient's benefit?	68	24	18	1
Do you know consent can be revoked at any time?	54	26	20	2

\*Type of consent which is necessary for the procedure is asked from the patient after introducing three types of consent.

**Table 2: Patients attitudes to consent in medical practice**

Statement	Agree (%)	Neutral (%)	Disagree (%)	Mean score
Consent reduces patient anxiety about the procedure.	62	9	29	3
It improves the doctor patient relationship.	91	6	3	2
Consent process helps to take a decision with understanding.	61	9	30	2
Disclosing information about potentially harmful risks may be worrying and disadvantageous for the patient.	38	14	48	3
Consent from the patient is not important as doctors know what is best for the patient.	38	8	54	3
While getting consent all the relevant information should be given to the patient irrespective of the educational level and social status of the patient.	62	11	27	2
While getting consent details should only be given if the patients asks for them.	34	5	61	3
Consent should be taken from both the relatives and patient even if the patient is capable of giving consent.	61	39	-	1

\* Scores vary from 1 (strong agreement) to 5 (strong disagreement) in the visual analogue scale. A value of 3 represent uncertain or neutral view

## DISCUSSION

Colombo North Teaching Hospital is situated north of the commercial capital of Sri Lanka and caters to a large urban and semi-urban population. The study population (n=420) consisted of a male to female ratio of 9:11. Around 2/5th of the study population represented the age group 18-40 years. More than 3/5th were Buddhist representing the trend in the Western province of Sri Lanka. The majority of them had secondary education.

### 1. Knowledge on 'consent'

A significant majority accepted that 'consent' is an important concept in medical practice. Qualitative meta-aggregation done by Convie revealed that the knowledge on consent helps to understand the consent process<sup>18</sup> which includes necessity of consent, rights of the patients, medical condition of the patient, available treatment options and outcome of the chosen option. A systematic review by Tam et al. for a 30-year duration has shown that 3/4th of participants understood the concept of consent in clinical trials<sup>19</sup>.

Analysis of the patient's knowledge on the necessity of consent and relevant types of consent showed that majority knew simple procedures such as auscultation does not need consent and if consent is needed, it can be given by a mere gesture. They knew that per rectal and per vaginal examination needs consent. Contrary to the belief that these procedures need informed consent, majority of patients stated that verbal consent is adequate. This may be due to the fact that in surgical wards, patients may have considered these procedures as routine therapeutic examinations with minimal or no complications and thus think that verbal consent would suffice. However a significant proportion were not aware that consent by gesture was inadequate in such situations. Majority of patients knew that consent is necessary and it should be written for complex investigations such as coronary angiography.

Most of the patients agreed that in a case of an unconscious patient, consent can be obtained from the next of kin and in an emergency the physician can proceed without consent to save the life of the patient. Almost all the patients agreed that physicians need to educate them about risks and complications, desired benefits and outcomes and alternative forms of the treatment.

Although most of the participants stated that they were aware of informed consent, only 2/3 of them

had the understanding that it is possible for a patient to refuse treatment, even if the physicians felt that it is for the patient's benefit. Further qualitative study is needed to assess whether they believe refusing treatment is morally or legally wrong.

Consent is a time-consuming dynamic process but it always reduces the burden on the physician<sup>20</sup> and intensifies the patient's satisfaction. In this study only half of patients knew that their consent can be withdrawn at any time before the procedure. Similar results were shown in other studies done in developing as well as developed countries<sup>21, 22</sup> indicating that a substantial number of patients did not recognize 'consent' as a dynamic process<sup>23</sup>. A study by Oonagh described that lack of knowledge on any aspect of the consent process is potentially a disadvantage to the patient<sup>24</sup>. It hinders the capability of the patient to obtain necessary clarifications from the physician. It also hinders the patient's participation in the decision-making process and makes them feel inferior, which hampers the objectives of the consent process.

### 2. Benefits of consent to the patient

Ronald *et al.* observed that most of the participants knew that consent is beneficial to them<sup>25</sup>. Our study showed that patients recognized the benefits of informed consent as 3/5th of them agreed that consent reduces patient anxiety about the procedure, while majority agreed that it improves the doctor patient relationship<sup>26</sup>. However, a significant proportion of patients were of the view that disclosing information about potentially harmful risks may be worrying and disadvantageous for them while others disagreed.

Expected outcomes of the consent process includes comprehension of the presented facts by the patient and involving them in the decision-making process. Among the participants, only 62.4% agreed that consent helps to take decisions with understanding. Others who didn't agree may have taken decisions without having adequate understanding. A literature review by Sherlock *et al.* concluded that the comprehension level of patients during consent is relatively low, especially among elderly patients<sup>27</sup>. Therefore, we need to establish a systematic approach in the consent taking process to improve the comprehension ability of the patient. Studies highlight that simple measures such as asking a patient to repeat what they have understood<sup>28,29</sup> spending more time in the consent taking process,<sup>30</sup> introducing learning aids and involvement of support staff<sup>27</sup> will help in this regard. Brody *et al.*

reported that a proper consent process will improve the quality of healthcare for the patient, 31 which is another advantage to the patient.

### 3. Physician knows the best

The concept of “physician knows best” is interconnected with medical paternalism which challenges the autonomy of the patient. However, having a reliable physician who is accountable and patient centred is worth it for patient management. Studies have shown that trusting doctors will improve the therapeutic outcomes of the patient<sup>32, 33</sup>. In our study, a substantial number of patients had given consent for the medical procedure because they trusted the physician. Even 2/5th have expressed that consent from the patient is not important as the physician knows what is best for the patient. Majority stated that consent should be taken from the patient by the physician and not by the nurses. This may indicate that a considerable number of Sri Lankan patients believe in the notion of ‘doctors know best’ and trust the physician’s knowledge. A study involving seldom-heard groups also were of the same view<sup>34</sup>. A study carried out by Masaki *et al.* on Japanese patients showed that a majority has selected family participation in decision making rather than individual decision making<sup>35</sup>. A Qualitative study done in six countries (Bangladesh, Sri Lanka, Nepal, Indonesia, Myanmar and India) by the WHO, having similar cultural basis revealed that patients consider physicians as duty bound responsible professionals<sup>36</sup>. This tendency could result in patients depending on their physicians and other healthcare professionals to make decisions on their behalf. Therefore, extreme care must be taken by the physicians for the best interest of the patient to prevent criticism and allegations of negligence and accusations of being solely responsible for a poor outcome.

### 4. Standard of disclosure

The amount of information needed to be disclosed to a patient for the ‘consent’ to be ‘informed’ has been and still is a contentious issue. There are three different legal standards available for the physician, namely ‘Professional standard’, which is the amount of information given by the reasonably prudent physician, ‘Objective Patient Based Standard’, which is the amount of information a reasonable patient would want and ‘Subjective Patient Based Standard’, which is the level of information desired by the individual patient<sup>37,38</sup>.

Most of the developed countries are guided by the standard of disclosure based on court rulings<sup>39</sup>. In

Sri Lanka, lack of court decisions and clear guidelines from the regulatory body have given the physicians freedom to decide on the ‘standard’ of disclosure. Since our study does not involve the physicians, analysis of data will not show us the standard the physicians use in the hospital. However, it may be possible for us to know what the patients think about the amount of information given in order for them to grant consent, by analysing their responses. Through this, we may be able to infer whether the physicians have fulfilled at least ‘reasonable patient’s standard’. From the patients 3/4th stated that they have received adequate information and have understood sufficiently about the treatment procedure to give consent. This indicates that the physicians have attempted to maintain ‘patient based standard’ with at least ¾ of the cases. The rest of the participants were not satisfied with the amount of information received. However, it has to be remembered that subjective satisfaction of patients does not necessarily mean that consent procedures are being properly followed in the hospital or that the patient had made an informed decision.

However, when they were asked whether ‘all the relevant information should be given to the patient irrespective of the educational level and social status’ most of them agreed with the mean of 2.42. When they were asked whether the ‘details should only be given if the patient asks for them’ some agreed while majority disagreed with the mean of 3.39. This may indicate that a majority of our participants believe in the ‘reasonable patient’s standard’ when it comes to the standard of disclosure. A study done by Hammami *et al.* on perception of information disclosure among patients revealed that disclosure of desired information related to the benefits and post-procedures were more than the disclosure of the risks and available alternatives to the patient<sup>40</sup>.

### 5. Responsibility of the patient and physician

In the consent process, it is important that the patients have received all the information that they wanted, comprehended the presented facts and felt that they were not deceived or compelled. Majority of our participants were satisfied that they had received adequate information and that they had understood adequately about the procedure. However, a study conducted in Sweden by Lynoe *et al.* had indicated that this perception is not always correct<sup>41</sup>. Comprehension of the patient depends on various factors such as age, education, intelligence, cognitive functions and anxiety<sup>41</sup>. Therefore, during the consent process, physicians should not

overestimate the patient's ability to comprehend. Strategies such as re-evaluation of the consent process is needed to improve a patient's comprehension, which will further minimize legal allegations and strengthen the ethical values.

Around 1/5th of the patients in this study accepted that they had given the consent without properly listening or reading the consent form. They might not have appropriately realized the importance of consent in their medical management and their responsibility as an equal partner in decision making. This is a significant draw back in the consent taking process.

## 6. Culture and patients' behavior

Sri Lanka applies concepts of medical ethics, including 'informed consent', which originated in the West. In most Western societies, individualism is preferred in decision making compared to some parts of the world, where they preferred community norms and family over individual rights<sup>42</sup>. Therefore, in some of the aspects of informed consent, there are differences between the theory and practice. We may find it difficult to implement the same western standards to a similar effect in our society. It is an accepted practice in Sri Lanka to divulge information of the old parents to their children without prior permission. Some parents are unaware of their disease and die without getting information of the disease from the children or receiving minimum information from the physician depending on the relatives wishes. Specially, this situation prevails in cancer patients. In Sri Lankan culture, patients are still reluctant to confront doctors with questions about a diagnosis or treatment regimes. This is a cultural difference in perceived 'autonomy' and 'self-determination' than in the West.

Unlike in the West, Sri Lankans still have the benefits of extended family. In a case of disease, public healthcare benefits alone are not adequate and family support is indispensable, especially in long term management. As a result, when a patient is hospitalized and decisions are made, not only their immediate family but also extended family are concerned. During a crucial decision, it is more likely to be a family centered decision rather than an individual-centered decision. A similar situation is seen in other Asian countries such as India<sup>7</sup>, Japan,<sup>35, 43</sup> Taiwan and China<sup>44, 45, 46</sup>. In such cultures, and in Sri Lanka, doctor-patient- family model is more appropriate while respecting the patient's wishes rather than patient centered consultation<sup>47, 48</sup>.

This trend is amply demonstrated in this study as 3/5th of patients were in favour of obtaining consent from themselves and their relatives, even if they were fully capable of granting consent. Most of the patients in our study stated that they had discussed with their relatives before giving consent for the medical procedure, even though it is not mandatory. However, they were aware of their rights as individuals, as almost all of them said that consent should be taken from the patient and not from the relatives if the patient has the capacity to give consent. Even though patients are aware of their rights, it appears that they are willing to share their autonomy of decision making with close relatives. A study by Al-Bahri *at el.* on the role of patients' families in cancer treatment decision-making had pointed out a similar situation even in Western countries<sup>49</sup>.

## CONCLUSION

Majority of patients were aware of the aspects of medical consent. However, analysis of their knowledge and attitudes indicated that they do not understand 'consent' as a dynamic process. Patients' attitudes towards consent is moving away from a paternalistic perspective to a more patient centered ideology. In the consent taking process, information disclosure to the patient should be maintained at "reasonable patient based standard" as indicated in the study. This study suggests that in the practice of obtaining consent, the physician needs to be attentive to the aspect of comprehension, as a considerable number of patients give consent without comprehension.

This study indicates that the cultural dimensions of the patient should be considered when obtaining consent. Therefore, in Sri Lanka, the doctor-patient-family model is more appropriate in the consent taking process to ensure that the patients' decision-making process is meaningful, while maintaining their self-respect.

## CONFLICTS OF INTEREST

The authors have no conflicts of interests to disclose

## ETHICAL ISSUES

None

## ACKNOWLEDGEMENT

Dr. D.C.G.A. Wirasinha for data collection.

## AUTHOR CONTRIBUTIONS

**WNSP:** Conceptualization, drafting proposal, Writing manuscript, Literature survey, Data analysis; **BPPP:** Improving concept, Improving proposal, Data analysis, Editing and reviewing of manuscript; **PP:** Improving concept, improving proposal, Editing and reviewing of manuscript.

## REFERENCES

- Guidelines on Medical and ethical conduct of Medical and Dental practitioners of Sri Lanka. Available from: <https://www.mc.lk/images/publications/EthicalConduct.pdf> pg 53-57 (Accessed 1<sup>st</sup> July 2021).
- Human tissue transplant act (No 48 of 1987) Sri Lanka. Available from: <https://www.lawnet.gov.lk/transplantation-of-human-tissues-3/> (Accessed 1st July 2021).
- World Medical Association declaration of Helsinki. Ethical principles for medical research involving human subjects. Available from: <http://www.ohsr.od.nih.gov/guidelines/helsinki.html>. (Accessed 1st March 2021).
- GMC (1998) Seeking patients' consent: The ethical considerations, General Medical Council, London. Available from: <https://www.gmc-uk.org/-/media/documents/patient-consent-1998---2008-55678021.pdf?la=en> (Accessed 1st March 2021).
- Nijhawan LP, Janodia MD, Muddukrishna BS, Bhat KM, Bairy KL, Udupa N, et al. Informed consent: Issues and challenges. *J Adv Pharm Technol Res.* 2013; 4(3):134–40. <https://doi.org/10.4103/2231-4040.116779>
- Hall DE, Prochazka AV, Fink AS. Informed consent for clinical treatment. *CMAJ.* 2012; 184(5):533–40. <https://doi.org/10.1503/cmaj.11212>
- Kirby MD. Informed consent: what does it mean? *J Med Ethics.* 1983 Jun;9(2):69-75. <https://doi.org/10.1136/jme.9.2.69>.
- Hammami MM, Al-Gaai EA, Al-Jawarneh Y, Amer H, Hammami MB, Eissa A, et al. Patients' perceived purpose of clinical informed consent: Mill's individual autonomy model is preferred. *BMC Med Ethics* [Internet]. 2014;15(1). Available from: <http://dx.doi.org/10.1186/1472-6939-15-2>
- Chima SC. Evaluating the quality of informed consent and contemporary clinical practices by medical doctors in South Africa: an empirical study. *BMC Med Ethics.* 2013; 14 Suppl 1(S1):S3. <https://doi.org/10.1186/1472-6939-14-S1-S3>
- Shamoo AE, Resnik DB. Strategies to minimize risks and exploitation in phase one trials on healthy subjects. *Am J Bioeth.* 2006;6(3):W1-13. <https://doi.org/10.1080/15265160600686281>
- Eyal N. Using informed consent to save trust. *J Med Ethics.* 2014; 40(7):437-44. <http://dx.doi.org/10.1136/medethics-2012-100490>. PMID: 25180355
- Shokrollahi K. Request for Treatment: the evolution of consent. *Ann R Coll Surg Engl.* 2010; 92(2):93–100. <https://doi.org/10.1308/003588410X12628812458851>
- Owen D, Aresti N, Mulligan A, Kosuge D. Customizable pre-printed consent forms: a solution in light of the Montgomery ruling. *Br J Hosp Med* (Lond). 2018; 79(2):97–101. <https://doi.org/10.12968/hmed.2018.79.2.97>
- Krishnamoorthy B, Yap K-H, R Critchley W, Nair J, Devan N, Barnard J, et al. A prospective randomized study comparing the current surgical informed consent form with a modified, pre-printed consent form. *Health Educ Care* [Internet]. 2016;1(1). Available from: <http://dx.doi.org/10.15761/hec.1000105>
- Pape T. Legal and ethical considerations of informed consent. *AORN J.* 1997 Jun;65(6):1122-7. [https://doi.org/10.1016/S0001-2092\(06\)62955-4](https://doi.org/10.1016/S0001-2092(06)62955-4)
- Akkad A, Jackson C, Kenyon S, Dixon-Woods M, Taub N, Habiba M et al. Patients' perceptions of written consent: questionnaire study *BMJ* 2006; <https://doi.org/10.1136/bmj.38922.516204.55>
- Knifed, E., Lipsman, N., Mason, W., & Bernstein, M. (2008). Patients' perception of the informed consent process for neurooncology clinical trials. *Neuro-oncology*, 10(3), 348–354. <https://doi.org/10.1215/15228517-2008-007>
- Convie1 J, Carson, E, McCusker, D, McCain, RS, McKinley N, Campbell WJ, et al., The patient and clinician experience of informed consent for surgery: a systematic review of the qualitative evidence. *BMC Medical Ethics.*(2020) 21:58 <https://doi.org/10.1186/s12910-020-00501-6>
- Tam NT, Huy NT, Thoa LTB, Long NP, Trang NTH, Hirayama K, et al. Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. *Bull World Health Organ.* 2015; 93(3):186-98H. doi: <http://dx.doi.org/10.2471/BLT.14.141390>
- Isabelle Budin-Ljøsne, Harriet J. A. Teare, Jane Kaye, Stephan Beck et al, Dynamic Consent: a potential solution to some of the challenges of modern biomedical research, *BMC Medical Ethics – open access Journal*, 2017 18:4. <https://doi.org/10.1186/s12910-016-0162-9>
- Lynoe N, Sandlund M, Dahlqvist G, Jacobsson L: Informed consent: study of quality of information given to participants in a clinical trial. *BMJ.* 1991, 303 (6803): 610-613. [10.1136/bmj.303.6803.610](https://doi.org/10.1136/bmj.303.6803.610). <https://doi.org/10.1136/bmj.303.6803.610>
- Krosin MT, Klitzman R, Levin B, Cheng J, Ranney ML: Problems in comprehension of informed consent in rural and peri-urban Mali, West Africa. *Clin Trials.* 2006, 3(3): 306-313. [10.1191/1740774506cn150](https://doi.org/10.1191/1740774506cn150). <https://doi.org/10.1191/1740774506cn150oa>.
- Information sheet. Guidance for Institutional Review boards and Clinical Investigators; A Guide to Informed Consent. United States Food and Drug Administration, 2011. Archived at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431>.
- Oonagh Corrigan, Empty ethics: the problem with informed consent, *Sociology of health and illness*, Volume25, Issue7, November 2003, Pages 768-792. <https://doi.org/10.1046/j.1467-9566.2003.00369.x>

25. Kiguba R, Kutwabami P, Kiwuwa S, Katabira E, Sewankambo NK. Assessing the quality of informed consent in a resource-limited setting: a cross-sectional study. *BMC Medical Ethics*. 2012 ;13(1):21. <https://doi.org/10.1186/1472-6939-13-21>
26. Greenfield S, Kaplan S, Ware JE Jr. Expanding patient involvement in care. Effects on patient outcomes. *Ann Intern Med*. 1985 ;102(4):520–8. <https://doi.org/10.7326/0003-4819-102-4-520>
27. Anne SS. Patients' recollection and understanding of informed consent: a literature review. *ANZ J Surg*. 2014; 84(4):207–10. <https://doi.org/10.1111/ans.12555>
28. Fink AS, Prochazka AV, Henderson WG, Bartenfeld D, Nyirenda C, Webb A, et al. Predictors of comprehension during surgical informed consent. *J Am Coll Surg*. 2010 ;210(6):919–26. <https://doi.org/10.1016/j.jamcollsurg.2010.02.049> PMID:20510800
29. Greening J, Bentham P, Stemman J, Staples V, Ambegaokar S, Upthegrove R, et al. The effect of structured consent on recall of information pre- and post-electro convulsive therapy: a pilot study. *Psychiatr Bull*. 1999 ;23(8):471–4. <https://doi.org/10.1192/pb.23.8.471>
30. Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: a systematic review. *JAMA*. 2004 ;292(13):1593–601. <https://doi.org/10.1001/jama.292.13.1593>
31. Brody DS, Miller SM, Lerman CE, Smith DG, Caputo GC. Patient perception of involvement in medical care: relationship to illness attitudes and outcomes. *J Gen Intern Med*. 1989; 4(6):506–11. <https://doi.org/10.1007/BF02599549> PMID:2585158
32. Fiscella K, Meldrum S, Franks P, Shields CG, Duberstein P, McDaniel SH, et al. Patient trust: is it related to patient-centered behavior of primary care physicians? *Med Care*. 2004 ;42(11):1049–55. <https://doi.org/10.1097/00005650-200411000-00003> PMID:15586831
33. Thom DH; Stanford Trust Study Physicians. Physician behaviors that predict patient trust. *J Fam Pract*. 2001; 50(4):323–8. PMID:11300984
34. Attitudes towards consent and decision making, Prepared for the General Medical Council by Ipsos MORI ,September 2018 <https://www.gmc-uk.org/.../about/attitudes-towards-consent-and-decision-making>
35. Masaki S, Ishimoto H, Asai A. Contemporary issues concerning informed consent in Japan based on a review of court decisions and characteristics of Japanese culture. *BMC Med Ethics*. 2014 ;15(1):8. <https://doi.org/10.1186/1472-6939-15-8> PMID:24495473
36. SEA-HSD-241Health Ethics in South-East Asia Ethical issues in clinical practice :A qualitative interview study in six Asian countries Volume 3,World Health Organization Regional Office for South-East Asia New Delhi December 2000, Available from <https://apps.who.int/iris/bitstream/handle/10665/205217/B0679.pdf?sequence=1&isAllowed=y> (Accessed 1st March 2021 ).
37. Murra B, Consent I. What Must a Physician Disclose to a Patient? *AMA Journal of ethics*, July 2012. Virtual Mentor. 2012;14(7):563–6. <https://doi.org/10.1001/virtualmentor.2012.14.7.hlwa1-1207> PMID:23351294
38. Dranseika V, Piasecki J, Waligora M. Relevant Information and Informed Consent in Research: In Defense of the Subjective Standard of Disclosure. *Sci Eng Ethics*; 23(1): 215–225. Published online 2016 Jan 20. <https://doi.org/10.1007/s11948-016-9755-4>.
39. Chan SW, Tulloch E, Cooper ES, Smith A, Wojcik W, Norman JE, Montgomery and informed consent: where are we now? *BMJ* 2017; 357 <https://doi.org/10.1136/bmj.j2224>. (Published 12 May 2017)
40. Hammami MM, Al-Jawarneh Y, Hammami MB, Al Qadire M., MC, *Med Ethics*. Information disclosure in clinical informed consent: "reasonable" patient's perception of norm in high-context communication culture,2014 ;15:3. <https://doi.org/10.1186/1472-6939-15-3>
41. Lloyd A, Hayes P, Bell PRF, Naylor AR. The Role of Risk and Benefit Perception in Informed Consent for Surgery. *Medical Decision Making*. 2001;21(2):141-149. <https://doi.org/10.1177/0272989X0102100207>
42. Christian P Selinger, The right to consent: is it absolute? *British Journal of Medical Practitioners*, 2009; 2(2) 50-54, <https://www.bjmp.org/files/june2009/bjmp0609selinger.pdf>
43. Ruhnke GW, Wilson SR, Akamatsu T, Kinoue T, Takashima Y, Goldstein MK, et al. Ethical decision making and patient autonomy: a comparison of physicians and patients in Japan and the United States. *Chest*. 2000 ;118(4):1172–82. <https://doi.org/10.1378/chest.118.4.1172> PMID:11035693
44. Lin ML, Kan WM, Chen CH. Patients' perceptions and expectations of family participation in the informed consent process of elective surgery in Taiwan. *Asian Nurs Res (Korean Soc Nurs Sci)*. 2012 ;6(2):55–9. <https://doi.org/10.1016/j.anr.2012.05.001> PMID:25030828
45. Lin ML, Wu JY, Huang MC. [The meaning of autonomy in Chinese culture: obtaining informed consent for operation]. *Journal of nursing*, 2008; 55(5):69–72.
46. Lu, L. (2009). 'I or we': family socialization values in a national probability sample in Taiwan, *Asian Journal of Social Psychology*, 12(2), 145e150. <https://doi.org/10.1111/j.1467-839X.2009.01276.x>
47. Cong, Y. (2004). Doctor-family-patient relationship: The Chinese paradigm of informed consent, *Journal of Medicine and Philosophy*, 29(2), 149e178 <https://doi.org/10.1076/jmep.29.2.149.31506>
48. Tsai, D. F. C. (2006). Eye on religion: Confucianism, autonomy and patient care. *Southern Medical Journal*, 99, 685e687. <https://doi.org/10.1097/01.smj.0000222398.48333.04>.
49. Al-Bahri A, Al-Moundhri M, Al-Azri M. The Role of Patients' Families in Cancer Treatment Decision-Making: perspectives among Eastern and Western families. *Sultan Qaboos Univ Med J*. 2017 ;17(4):e383–5. <https://doi.org/10.18295/squmj.2017.17.04.001> PMID:29372077